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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,268	04/05/2000	Todd M. Boyce	285-79 CON	6472

7590 04/02/2003
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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/543,268

Applicant(s)

BOYCE ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-21, 23-43, 45-61, 63-80 and 82-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-21, 23-43, 45-61, 63-80 and 82-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-11, 13, 14, 19-21, 23, **24**, 34-43, 45, 56-61, 63, 74-80, 82 and 93-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyle (US 5,061,286) wherein demineralized bone particles have had there minerals removed such that the surfaces thereof are collagen. In addition, the particles are linked together with the binder such as cyanoacrylate; see especially column 2, lines 63-68 and column 4, lines 12-20.

The Examiner posits that the adhesives or binders inherently act via covalent or non-covalent bonds. Even if the adhesives or binders were said to not act through covalent bonds, since adhesives and binders of Lyle can act via hydrogen bonding, Van der Waals bonds, ionic bonds, and other non-covalent bonds, the Examiner posits that the present claims are inherently met in this regard.

With regard to claim 6 specifically, the figures show a ring shaped cross-section around the hip implant stem.

With regard to claims 1-7, 9-10, 23, 45, 63, and 82, the material of Lyle is a solid material so it inherently has a tensile strength even though one is not disclosed. Since the Office does not have testing facilities to determine the tensile strength thereof, the Examiner hereby asserts that the tensile strength of Lyle is within the claimed range and hereby burdens the Applicant to show otherwise.

With regard to claims 13, 14, **24**, 36, 40, 58, and 76, the limitations set forth in these claims are process limitations even though the claims are drawn to a product. For this reason, the Examiner asserts that the claimed product is fully met by Lyle even though a different method was used to make it because bonds with the collagen and binding agent are present; see MPEP 2113 which is incorporated herein by reference thereto.

Claims 1-7, 9-21, 23-43, 45-61, 63-80, and 82-134 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boyce et al (US 5,899,939); see the entire document.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle (US 5,061,286) alone. Lyle discloses the use of a binding agent in general and of a crosslinking molecule of cyanoacrylate specifically but does not disclose the

use of the particular crosslinking agents as claimed. However, the Examiner posits that it would have been obvious to use another crosslinking agent in view of the broad teaching of Lyle for a binding agent absent some showing that the particular agent had some unexpected/unobvious result.

Response to Arguments

Applicant's arguments filed January 30, 2003 have been fully considered but they are not persuasive.

In response to the traversal of the Lyle 35 USC 102(b) rejection that Lyle does not teach binding of particles to each other by chemical linkages, the Examiner posits that the cement or adhesive of Lyle provides the chemical linkages to bind the particles together. Furthermore, there is no claim language, which precludes an intermediate chemical structure.

Applicant argues that the chemical linkages of Lyle are within the adhesive and not with the collagen of the demineralized bone. However, even though the Examiner is not convinced of this fact, the Examiner notes that the present claims do not require covalent linkages only chemical linkages between surface-exposed collagen. Since adhesives and binders can act via hydrogen bonding, Van der Waals bonds, ionic bonds, and other non-covalent bonds, the Examiner posits that the present claims are inherently met in this regard.

It is noted that claim 24 was added to the rejection statement of Lyle because it was inadvertently left out even though it was explained above. Since Applicant did not comment on the inconsistency between the rejection statement and the explanation

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statement, the Examiner posits that this does not present a new issue. Nonetheless, if Applicant objects to this change as being a new ground, he can consider it withdrawn from the rejection statement.

The declaration filed on January 30, 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Boyce et al (US 5,899,939) reference.

(1). It was not made by all the inventors and there is no showing that Todd Boyce is the sole inventor of the claims under rejection; see MPEP 715.04.

(2). Claim 1 is not commensurate with the scope of the invention shown in the declaration in that claim 1 is drawn to a broader invention. It is noted that 4 of the 5 examples in Exhibit A are to sheet forms of the implant, yet claim 1 is drawn to any solid aggregate. The other example (Example 2) is not drawn to "elements bonded through chemical linkages to the surface-exposed collagen" as claimed. In Example 2, there is apparently no chemical bonding. Even though claim 1 is not commensurate with the declaration invention, there is no showing that the difference is obvious; see MPEP 715.02, 3rd paragraph (August 2001 edition). For this reason, the declaration is considered insufficient with regard to claim 1 and its dependent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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